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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,106	02/17/2004	James B. Dale	481112.410C1	8037
500 7590 12/04/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 12/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/780,106	<b>Applicant(s)</b> DALE, JAMES B.	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3, 4 and 7-29 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 4, 7, 10, 11 and 15-17 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 8, 9, 12-14 and 18-29 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/01/07</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
|---|---|

## **RESPONSE TO APPLICANT'S AMENDMENT**

### **Applicant's Amendment**

- 1) Acknowledgment is made of Applicant's amendment filed 10/01/07 in response to the non-final Office Action mailed 03/29/07. With this, Applicant has amended the specification and the claims.

### **Status of Claims**

- 2) Claims 1, 2, 5 and 6 have been canceled via the amendment filed 10/01/07.  
Claims 3, 7-19, 22, 23 and 25-27 have been amended via the amendment filed 10/01/07.  
New claims 28 and 29 have been added via the amendment filed 10/01/07.  
Claims 3, 4 and 7-29 are pending.  
Claims 3, 8, 9, 12-14 and 18-29 are under examination.

### **Information Disclosure Statement**

- 3) Acknowledgment is made of Applicant's information disclosure statement filed 10/01/07. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Terminal Disclaimer**

- 4) Acknowledgment is made of Applicant's submission of a terminal disclaimer filed 10/01/07 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patents 6,716,433.

### **Prior Citation of Title 35 Sections**

- 5) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

- 7) The objection to the specification made in paragraph 7 of the Office Action mailed 03/29/07

is withdrawn in light of Applicant's amendments to the specification.

### **Rejection(s) Withdrawn**

- 8)** The rejection of claims 3, 9, 12-14 and 18 made in paragraph 9 of the Office Action mailed 03/29/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7, 9, 10 and 15 of US patent 6,716,433 ('433), is withdrawn in light of Applicant's submission a terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patents 6,716,433.
- 9)** The provisional rejection of claims 22 and 23 made in paragraph 10 of the Office Action mailed 03/29/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48 and 76 of the co-pending application 10/284,400, is withdrawn.
- 10)** The rejection of claim 3 made in paragraph 11 of the Office Action mailed 03/29/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicant's amendment to the claim.
- 11)** The rejection of claim 25 made in paragraph 12 of the Office Action mailed 03/29/07 under 35 U.S.C § 112, first paragraph, as containing new matter, is withdrawn in light of Applicant's amendment to the claim.
- 12)** The rejection of claim 3 and those dependent therefrom made in paragraph 13 of the Office Action mailed 03/29/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicant's amendment to claim 3.
- 13)** The rejection of claim 3 made in paragraph 15(a) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 14)** The rejection of claim 3 made in paragraph 15(b) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 15)** The rejection of claim 3 made in paragraph 15(c) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 16)** The rejection of claim 22 made in paragraph 15(d) of the Office Action mailed 03/29/07

under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**17)** The rejection of claim 23 made in paragraph 15(e) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**18)** The rejection of claim 26 made in paragraph 15(f) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**19)** The rejection of claim 27 made in paragraph 15(g) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**20)** The rejection of claims 8, 9, 12-14 and 18-27 made in paragraph 15(h) of the Office Action mailed 03/29/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

### **New Rejection(s) Necessitated by Applicant's Amendment**

#### **Double Patenting Rejection**

**21)** Claims 3, 8, 9, 12-14, 18, 22-24 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7, 13, 14, 17, 20, 47-53 and 57-59 of the co-pending application 11831638 filed on 07/31/07 *after* the mailing of the previous Office Action.

Claim 3 is drawn to a hybrid fusion polypeptide comprising a multivalent immunogenic portion comprising six immunogenic amino-terminal polypeptides from six different Group A streptococcal serotypes, each at least 10 (i.e., inclusive of 35, 40 or 50) amino acids in length, and a carboxy-terminal immunogenic polypeptide carboxy-terminal to the multivalent portion which carboxy-terminal immunogenic polypeptide is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent portion. The open claim language 'comprises' in claim 3 permits the presence of additional amino-terminal peptides or polypeptides of Group A streptococcal M protein in the claimed hybrid fusion polypeptide. Claims 5-7, 13 and 14 of the co-pending application 11831638 encompass a hybrid polypeptide comprising 7 different linked

(i.e., fused) amino terminal peptides from M2, M11, M22, and/or M28, each at least 35, 40 or 50 amino acids in length, wherein the hybrid polypeptide has an amino-terminal peptide that is reiterated as a carboxy-terminal peptide and elicits an immune response against M2, M22, M11 and/or M28, and therefore fall within the scope of the instant claims 3, 8, 9, 12, 13 and 28. Instant claims 14 and 18 encompass the hybrid polypeptide claimed in claims 20 and 17 of the co-pending application. Likewise, the composition claimed in claims 47-53, 57 and 58-59 falls within the scope of the instant claims 22, 23 and 24 respectively.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**22)** Claims 3, 8, 9, 12-14 and 18-29 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 3 is vague, indefinite, confusing and/or inconsistent in scope in the limitation: 'at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide' (see lines 10 and 11). The six immunogenic amino-terminal polypeptides of Group A streptococcal M protein recited earlier in the claim are confined to the multivalent immunogenic portion. It is unclear whether or not the above-identified at least one immunogenic amino-terminal polypeptide is from outside the multivalent immunogenic portion, or whether Applicant is trying to convey that --at least one of the six different Group A streptococcal serotypes is serotype 2, serotype 11, serotype 22, or serotype 28--.

(b) Claim 3 is indefinite in the limitation: 'a Group A streptococcal serotype 2'. Is the purpose of the limitation 'a' to indicate that there are more than one serotype 2 of Group A streptococcus, and that the recited at least one of immunogenic amino-terminal polypeptides of the fusion polypeptide is required to be from one of those serotypes 2? If not, for the purpose of distinctly claiming the subject matter, it is suggested that Applicant delete the limitation 'a'.

(c) Analogous rejection and criticism apply to claims 8, 9, 12, 13 and 28.

(d) Claim 8 is vague, indefinite, and/or appears to lack proper antecedent basis in the limitation: 'fusion polypeptide according to claim 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 2'. Claim

8 depends from the amended claim 3, which already recites that 'at least one of immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 2'. Does it mean that the fusion polypeptide of claim 8 comprises an additional immunogenic amino-terminal polypeptide from Group A streptococcal serotype 2 other than the serotype 2 amino-terminal polypeptide recited in the base claim 3?

(e) Analogous rejection and criticism apply to claims 9, 12, 13 and 28.

(f) Claim 14 is vague and indefinite in the limitation: 'fusion polypeptide elicits an immune response comprising opsonic antibodies against Group A streptococcal M protein ..'. Claim 14 depends from claim 3 wherein at least one of the immunogenic amino-terminal polypeptides is limited to specific Group A streptococcal serotype 2, 11, 22, or 28. Does it mean that the claimed hybrid fusion polypeptide elicits opsonic antibodies against generic streptococcal M protein of any serotypes, i.e., against serotypes that are not included within the scope of claim 3?

(g) Claims 8, 9, 12-14 and 18-29, which depend directly or indirectly from claim 3, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### Remarks

**23)** Claims 3, 8, 9, 12-14 and 18-29 stand rejected.

It is suggested that Applicants delete the comma from line 1 of claim 3.

**24)** Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**25)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**26)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA and CANADA) or 571-272-1000.

**27)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

November, 2007

  
S. DEVI, PH.D.  
PRIMARY EXAMINER